

Rulemaking Record for the Procedures for Detection and Quantitation
Proposed Rule
E-Docket # OW-2003-0002

<u>DCN</u>	<u>Section</u>	<u>Type of Item</u>	<u>Title</u>	<u>Date</u>	<u>Recipient</u>	<u>Sender</u>	<u>Number of Pages</u>	<u>Source</u>
323	A	METHOD	EPA Method 1631, Revision B: Mercury in Water by Oxidation, Purge and Trap, and Cold Vapor Atomic Fluorescence Spectrometry	05/1999	Record	USEPA	38	U.S. EPA, Office of Water, Engineering and Analysis Division (4303), Washington, D.C. EPA 821-R-99-005 (See Method 1631, III.G.1)
324	A	FRN	Appendix B to Part 136-Definition and Procedure for the Determination of the Method Detection Limit-Revision 1.11	10/26/1984	Record	USEPA	2	Federal Register (49 FR 43234)
329	A	FRN	Guidelines Establishing Test Procedures for the Analysis of Pollutants; Proposed Regulations	12/3/1979	Record	USEPA	113	Federal Register (44 FR 69463)
337	A	DOC	Definition and Procedure for the Determination of the Method Detection Limit - Rev. 1.11	01/21/1981	Record	USEPA	7	USEPA- ORD
381	A	FRN	Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act; Final Rule and Interim Final Rule, and Proposed Rule.	1984	Record	USEPA	220	Federal Register (49 FR 43234)
382	A	FRN	National Primary Drinking Water Regulations - Synthetic Organic Chemicals Monitoring for Unregulated Contaminants; Final Rule	1987	Record	USEPA	24	Federal Register (52 FR 25690)
383	A	FRN	National Primary Drinking Water Regulations - Synthetic Organic Chemicals and Inorganic Chemicals; Final Rule	1992	Record	USEPA	75	Federal Register (57 FR 31776)

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384	A	FRN	OMB Circular A-119: Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities	1998	Record	USEPA	14	Federal Register (63 FR 8546)
385	A	FRN	Guidelines Establishing Test Procedures for the Analysis of Pollutants; Measurement of Mercury in Water (EPA Method 1631, Revision B); Final Rule	1999	Record	USEPA	17	Federal Register (64 FR 30417) - See Method 1631-III, A.1
386	A	AGREEMENT	October 19, 2000 Settlement Agreement Between the Alliance of Automobile Manufacturers, Inc., the Chemical Manufacturers Association, and the Utility Water Act Group, the American Forest & Paper Association, and the US Environmental Protection Agency.	10/19/2000	Record	USEPA	12	EPA
112	B1	DOC	Study Plan - Evaluation of Statistical Approaches to Developing Detection and Quantitation Limits - draft	01/19/1996	USEPA	Lynn Riddick	6	DynCorp
135	B1	LETTER	Low Level Detection Reporting Requirement Information Request	01/13/1998	Wisconsin Laboratories	John Sullivan	1	Wisconsin Department of Natural Resources
191	B1	DOC	Peer Review of the Plan for the Assessment of Detection and Quantitative Limits under Section 304(h) of the Clean Water Act	02/2002	USEPA	Versar	156	Versar
269	B1	DOC	Plan for the Assessment of Detection and Quantitative Limits under Section 304(h) of the Clean Water Act	12/10/2001	Record	USEPA	18	USEPA
281	B1	LETTER	DL/QL Study Plan	01/07/2002	Maria Gomez-Taylor	Steven Koorse	10	Hunton & Williams
326	B1	DOC	Plan for the Assessment of Detection and Quantitation Limits Under Section 304(h) of the Clean Water Act	04/2002	Record	USEPA Office of Water	21	USEPA Office of Water (EPA-821-R-02-010)

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389	B1	DOC	Response to Peer Review Comments on the Draft Assessment of Detection and Quantitation Limits under Section 304(h) of the Clean Water Act	04/2002	Record	USEPA	EPA		
001	B2	DOC	Interlaboratory Validation of EPA 1600 Series Methods: Draft EPA Method 1638 for Analysis of Metals in Water by Inductively Coupled Plasma-Mass Spectrometry (ICP-MS)	11/2000	Record	N.T. Whiddon	358		EPRI Technical Report 1000824
119	B2	ARTICLE	IUPAC Recommendations for Defining and Measuring Detection and Quantification Limits	1994	Record	LA Currie, W. Horwitz	3		Analuses Magazine 22: 24-26
131	B2	ARTICLE	Nomenclature for the Presentation of Results of Chemical Analysis (IUPAC Recommendation 1994)	1994	Record	L.A. Currie, G. Svehla	14		Pure & Applied Chemistry 66: 595-608
144	B2	ARTICLE	Limit of Detection: A Closer Look at the IUPAC Definition	06/1983	Record	Gary Long, J.D. Winefordner	8		Analytical Chem. 55: 712-724
145	B2	METHOD	Standard Practice for a 99%/95% Inter-Laboratory Detection Estimate (IDE) for Analytical Methods with Negligible Calibration Error	03/1996			11		ASTM 6091-97
170	B2	ARTICLE	Nomenclature in Evaluation of Analytical Methods Including Detection and Quantifation Capabilities (IUPAC Recommendations 1995)	1999	Record	L.A. Currie	22		Analytica Chimica Acta 391: 105-126
243	B2	ARTICLE	Guidelines for Calibration in Analytical Chemistry-Part I. Fundamentals and Single Component Calibration (IUPAC recommendations 1998)	04/98	Record	K. Danzer, L.A. Currie	22		Pure and Applied Chemistry 70: 993-1014

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252	B2	ARTICLE	A Statistical Overview of Standard (IUPAC and ACS) and New Procedures for Determining the Limits of Detection and Quantification: Application to Voltammetric and Stripping Techniques (Technical Report)	1997	Record	J. Mocak, A.M. Bond, S. Meitchell, G. Scollary	32	Pure and Applied Chemistry 69: 297-328
268	B2	LETTER	Detection/Quantification Assessment	08/17/2001	Geoff Grubbs	Steve Koorse	3	Hunton & Williams
311	B2	REFERENCE	Detection Limits	2002	Record	A.H. El-Shaarawi, W.W. Piegorsch	14 select	Encyclopedia of Environmetrics Vol. 1 A-D, pp.504-515
313	B2	DOC	Summary Report: Peer Review of the "Technical Support Document for the Assessment of Detection and Quantitation Concepts"	09/2002	USEPA	Versar	191	Versar
325	B2	REPORT	Results of the Interlaboratory Validation Study of EPA Method 1631	3/1998	Record	USEPA	78	USEPA
327	B2	OPINION	Daubert v. Merrell Dow Pharmaceuticals, Inc.; No. 92-102	6/28/1993	Record	USEPA	18	509 U.S. 579, 113 S.Ct. 2786
328	B2	OPINION	Kumho Tire Company, LTD. V. Carmichael; No. 97-1709	3/23/1999	Record	USEPA	15	526 U.S. 137, 119 S.Ct. 1167
344	B2	PAPER	Levels of Method Performance Documentation	09/12/1996		EMMC QA Panel	2	EMMC QA Panel
373	B2	REPORT	Determination of Interlaboratory Detection and Quantification Levels for Polychlorinated Biphenyls	01/2002	Record	J.H. Phillips, J. Gabrosek, R. Rediske	140	Michigan Manufacturers Association
375	B2	DOC	Draft Technical Support Document for Proposal of Detection and Quantitation Regulations under the Clean Water Act	08/2002	Record	USEPA Office of Water	80	USEPA Office of Water
391	B2	REPORT	Results of the Interlaboratory Validation Study of EPA Method 1638 - DRAFT	10/2000	Record	USEPA	203	EPA
392	B2	REPORT	Results of the Interlaboratory Validation Study of EPA Method 1631		Record	N.T. Whiddon		EPRI

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397	B2	METHOD	Standard Practice for Interlaboratory Quantitation Estimate (ASTM Practice D 2777)	2000	Record	ASTM	14	ASTM D-6512-00
398	B2	DOC	Quantifying Uncertainty in Analytical Measurement- 2nd Ed.	2000	Record	S.L.R. Ellison, M. Rosslein, A. Williams	124	Eurachem / CITAC, 2000
399	B2	DOC	VAM Project 3.2.1 Development and Harmonisation of Measurement Uncertainty Principles- Part (d): Protocol for Uncertainty Evaluation from Validation Data	2000	Record	V.J. Barwick, S.L.R. Ellison	97	LGC/VAM/1998/088
400	B2	DOC	Science Policy Council Handbook (EPA-100-B-98-00)	01/98	Record	USEPA		USEPA
401	B2	DOC	Science Policy Council Handbook (EPA-100-B-00-001)	2000	Record	USEPA		USEPA
402	B2	DOC	Handbook for Analytical Quality Control in Water and Wastewater Laboratories	06/72	Record	USEPA	116	USEPA National Environmental Research Center
403	B2	DOC	Guide to the Expression of Uncertainty in Measurement	1993			2	ISO, Geneva (ISBN 92-67-10188-9)
404	B2	BOOK	Statistical Intervals	1991	Record	Hahn and Meeker	1 select	Wiley
405	B2	BOOK	Concepts on Non-parametric Theory	1981	Record	Pratt and Gibbons	1 select	Springer-Verlag
406	B2	DOC	Guidance on Evaluation, Resolution, and Documentation of Analytical Problems Associated with Compliance Monitoring	1993	Record	USEPA		EPA 821-B-93-001
407	B2	DOC	Draft National Guidance for the Permitting, Monitoring, and Enforcement of Water Quality-based Effluent Limitations Set Below Analytical Detection/Quantitation Levels	1994	Record	USEPA	104	USEPA
408	B2	DOC	Guidance for the Implementation and Use of EPA Method 1631 for the Determination of Low-Level Mercury (40 CFR Part 136)	2001	Record	USEPA	52	See Method 1631-IV, B.2

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409	B2	BOOK	Statistical Manual of the Association of Official Analytical Chemists	1975	Record	W.J. Youden, E.H. Steiner	2 select	AOAC-International
410	B2	BOOK	Introduction to Mathematical Statistics and Its Application	1999	Record	Larsen and Marx	2 select	Prentice Hall
411	B2	BOOK	Introduction to Mathematical Statistics	1995	Record	Hogg and Craig	2 select	Prentice Hall
413	B2	BOOK	Statistics for Experimenters	1978		Box, G.E.P	1 select	
416	B2	LETTER	coverletter for the draft Technical Support Document submitted to Hunton & Williams for review	08/13/2002	Steven Koorse	Maria Gomez-Talyor	1	USEPA
417	B2	LETTER		06/27/2002	Maria Gomez-Talyor	Steven Koorse	3	Hunton & Williams
418	B2	DOC	EPA Response to Peer Review Comments Received on EPA's Draft Assessment of Detection Limit Concepts	02/25/2003	Record	EPA	38	USEPA
100	C	LETTER	Quantification Levels (includes Quantification Issue: Historical Overview)	05/30/1996	Robert Perciasepe	Inter-Industry Analytical Group	8	Inter-Industry Analytical Group
101	C	LETTER	Vote against Standard Method 1030E	08/13/1996	Ken Osborn	Paul Britton	14	USEPA
102	C	LETTER	Quantification Levels	3/30/1998	Robert Perciasepe	Inter-Industry Analytical Group	4	Inter-Industry Analytical Group
103	C	NOTES	Summary of EPA and Inter-Industry Analytical Group Meeting - April 26, 1996	11/11/1997			30	USEPA
105	C	EMAIL	ML meeting summary	07/01/1998	William Telliard	Larry LaFleur	2	WCRC-NCASI
106	C	LETTER	Response to ASTM Committee D-19 on Water "Inter-laboratory Quantitation Estimate" (IQE) - DRAFT	01/14/1999	James Lichtenberg	William Telliard	1	USEPA
108	C	MEMO	Resolution of Quantification/ Detection Level Issues	01/26/1996	Bill Telliard	Jim Taft	1	USEPA

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113	C	PRESENT	The Calculation of Method Detection Limits: An Alternative to the EPA Procedure Using Quality Control Precision Data	08/11/1993	Record	Kenneth Osborn	9	WEF Specialty Conference Series, 08/11/93, Santa Clara, CA
139	C	LETTER	Quantitative Meeting	05/28/1996	Tudor Davies	Inter-Industry Analytical Group	2	Inter-Industry Analytical Group
146	C	LETTER	Interlaboratory Quantitative Estimate (IQE) negative vote	03/31/1998	Nancy Grams of ASTM	William Telliard	5	USEPA
150	C	COMMENT	American Water Works Association - Review and Comment Letter Ballot - SMLB #107-20	02/10/1998	AWWA	Richard Reding	5	USEPA
151	C	MEMO	Use of the Minimum Levels (ML) in Water Quality Standards	05/04/1998	George Golliday of EPA Region 3	William Telliard	2	USEPA
153	C	LETTER	List of AML issues for discussion at EPRI meeting on 04/26/96	04/16/1996	Babu Nott	William Telliard	3	USEPA
154	C	MEMO	Summary of April 26, 1996 meeting with Inter-Industry Analytical Group	05/1996	Tudor Davies	William Telliard	9	USEPA
155	C	LETTER	Response to IIAG letter dated 05/28/96 to Tudor Davies	06/20/1996	Babu Nott	William Telliard	1	USEPA
157	C	MEMO	Summary of phone calls and meetings associated with the ASTM D19 Committee meetings in Louisville, KY, June 13-17, 1999	06/21/1999	Bill Telliard	Dale Rushneck	2	Interface
160	C	PRESENT	Quantitation / Detection Limits for the Analysis of Environmental Samples	1990	Record	WG Krochta, LI Bone, BA Cucherini, TL Dawson, KJG Hillig, RA Javick, NE Prange, BM Hughes, FI Saksa,	27	Norfolk Conference
224	C	LETTER	Quantification Levels	09/11/1998	Charles Fox	Inter-Industry Analytical Group	5	Inter-Industry Analytical Group

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225	C	BALLOT	Negatives on D19.02 items in ASTM Ballot D19 (98-02) Item 2 - Interlaboratory Quantitation Estimate	1998	Record	ASTM	13	ASTM	
267	C	TRANSCRIPT	Detection/Quantitation Workshop transcript from Norfolk 2001 Conference	05/10/2001	Record	DynCorp	61	DynCorp	
268	C	NOTES	Detection/Quantification Study Planning Matrix	08/17/2001	Geoff Grubbs	Steve Koorse	11	Hunton & Williams	
282	C	LETTER	Detection/Quantification Assessment	08/17/2001	Geoffrey Grubbs	Steven Koorse	10	Hunton & Williams	
308	C	PRESENT	Method Detection Limits: Application to Organic Environmental Chemistry Data	08/2002	Record	T.L. Wade, J.L. Sericano, Y. Qian, G. Wolff, G. Denoux	12	ACS Annual Meeting, Boston, MA 2002	
309	C	PRESENT	Environmental Quality: Closing the Decision-Data Loop	8/21/2002	Record	Deana Crumbling	37	224th ACS National Meeting, Boston, MA	
320	C	CORRESPOND	DL/QL Assessment	11/11/2002	Maria Gomez-Taylor	James Christman	3	Hunton & Williams	
330	C	EMAIL	Replicates for MDL	02/03/2003	Dale Rushneck	John Glaser	2	Email 02/03/03	
331	C	MEMO	MDL Improvement - DRAFT	7/16/1998	Joe Slayton	William Telliard	2	USEPA	
332	C	LETTER	Invitation to present at meeting on 04/26/96	04/26/1996	Babu Nott	William Telliard	3	USEPA	
333	C	LETTER	Thank you for allowing EPRI to present at the 04/26/96 meeting	05/03/1996	James Taft	Babu Nott	1	EPRI	
334	C	PRESENT	EPRI's presentation materials from the 04/26/96 meeting	04/26/1996	Record	Babu Nott	19	EPRI	
335	C	LETTER	Response to "Analytical Detection and Quantification" letter dated 04/30/97	06/09/1997	William Sonntag Jr.	Robert Perciasepe	3	USEPA	
339	C	LETTER	Negative on Interlaboratory Quantitation Estimate (IQE)	10/10/1999	ASTM D-19 Members	William Telliard, Richard Reding, Dale Rushneck	3	USEPA, Interface	
340	C	PRESENT	Statistically Valid Detection Limits and Quantitation Limits		Record	David Coleman	110	Alcoa	

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341	C	MEMO	Detection/Quantitation Limit Issues; EMMC Draft Paper Dated September 10, 1996 - DRAFT		EMMC QA Panel	William Telliard	2	USEPA
342	C	PAPER	Detection/Quantitation Limit Issues - DRAFT	09/10/1996		EMMC QA Panel	4	EMMC QA Panel
343	C	MEMO	Approval of EMMC Levels of Method Performance Documentation	09/12/1996		Nancy Barmakian, Wendy Blake-Coleman, Laurie Schuda	3	EMMC QA Panel
345	C	PRESENT	Estimation of Precision of Low Concentration Chemical Analytical Measurements and Establishing Detection and Quantification Limits	04/01/1997	Record	Henry Kahn, Kathleen Stralka, Raphael Kuznetsovski	31	USEPA 12th Annual Conference on Statistics, April 1-3, 1997
346	C	MEMO	August 2-3, 1995 Meeting on the Draft "National Guidance for the Permitting, Monitoring, and Enforcement of Water Quality-Based Effluent Limitations Set Below Analytical Detection or Quantitation Levels"	07/14/1995	Meeting Attendees	James Taft	16	USEPA
347	C	PAPER	The Problem with EPA's MDLs and MLs	06/21/1995	USEPA	R. Gibbons, R. Maddalone, D. Coleman, B. Nott, L. LaFleur, J. Rice	29	Inter-Industry Analytical Group
348	C	PAPER	An Alternative Minimum Level	06/21/1995	USEPA	R. Gibbons, R. Maddalone, D. Coleman, B. Nott, L. LaFleur, J. Rice	61	Inter-Industry Analytical Group
352	C	PAPER	White Paper on EPA's Draft "National Guidance for the Permitting, Monitoring, and Enforcement of Water Quality-Based Effluent Limitations Set Below Analytical Detection/Quantitation Levels"		Michael Cook	Steven Koorse	13	Hunton & Williams

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355	C	PRESENT	Much Ado about Next to Nothing - Judging Compliance at the Limit of Detection	05/14/1991	Record	P.M. Berthouex	16	64th Annual Meeting of the Central States Water Pollution Control Association
367	C	PAPER	A Simple Rule for Judging Compliance Using Highly Censored Samples	01/1991	Record	P. M. Berthouex, Ian Hau	19	The Consortium for Water Pollution Control Research
368	C	PAPER	The Method Detection Limit: Fact or Fantasy?	1997	Record	Richard Burrows, Jack Hall	4	15th Annual Waste Testing and Quality Assurance Symposium
369	C	PRESENT	EPA's Efforts on Detection and Quantitation	06/2001	Record	Maria Gomez-Taylor	21	2001 AOAC Meeting
370	C	PRESENT	Hypothesis Tests with Censored Data	04/2001	Record	USEPA Quality Staff	39	2001 Annual EPA QA Conference, St. Louis, MO
371	C	PRESENT	Analyzing Censored Data	04/2001	Record	USEPA Quality Staff	42	2001 Annual EPA QA Conference, St. Louis, MO
372	C	PRESENT	Detection Limits	04/2001	Record	USEPA Quality Staff	36	2001 Annual EPA QA Conference, St. Louis, MO
374	C	PRESENT	Alternative Estimates of Detection	1997	Record	H.D. Kahn, C.E. White, K. Stralka, R. Kuznetsovski	14	20th Annual Conference on Analysis of Pollutants in the Environment, May 7-8, 1997, Norfolk, VA
376	C	MEMO	Updated Annotated Bibliography	02/27/1998	Chuck White	Raphael Kuznetsovski	30	SAIC
377	C	LETTER	Thank for 10/17/96 IIAG meeting (with AML software user manual)	10/23/96	Sheila Frace	Babu Nott	1+att(25p)	Inter-Industry Analytical Group
378	C	LETTER	Summary of 10/16/96 IIAG-EPA meeting	11/5/96	Sheila Frace	Babu Nott	9	Inter-Industry Analytical Group
379	C	PRESENT	Quantification Level Properties Explanations	10/17/96	IIAG	EAD	16	USEPA
380	C	LETTER	Discussions with IIAG, suggested meeting	09/17/96	Sheila Frace	Babu Nott	5	IIAG
387	C	CORRESPOND	DL/QL Assessment	06/06/2002	Sheila Frace	Steven Koorse	5	Hunton & Williams

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415	C	MEMO	June 6, 2002 Letter from Steven J. Koorse (Hutton Williams) on behalf of the Inter-Industry Analytical group (IIAG) regarding EPA's ongoing assessment of detection and quantitation limit	2/2003	Record	Maria Gomez-Taylor	3	USEPA
419	C	LETTER	IIAG Proposal for Sensitivity Test and Full-Range Interlaboratory Validation Study	12/27/02	Maria Gomez-Taylor	James Christman	10	Hunton & Williams
130	D	PAPER	Some Statistical and Conceptual Issues in the Detection of Low Level Environmental Pollutants	07/12/1995	G.P. Patil	Robert Gibbons	43	University of Illinois at Chicago, Biometrics Laboratory
134	D	DOC	Analytical Detection Limit Guidance and Laboratory Guidance for Determining Method Detection Limits	04/1996	Record	Wisconsin Dept. Natural Res.	33	Wisconsin Dept. Natural Res. PUBL-TS-056-96
135	D	REPORT	Method Detection Limit Survey Results and Analysis	12/1998	Record	Kerilynn Carden	36	Wisconsin Dept. Natural Res. PUBL-SS-930-98
147	D	GUIDELINE S	Guideline for Calibration in Analytical Chemistry- Part 1. Fundamentals and Single Component Calibration	1998	Record	IUPAC	21	IUPAC
270	D	TEXT	Statistical Methods of Detection and Quantification of Environmental Contamination	2001	Record	Robert Gibbons, David Coleman	2 select	John Wiley & Sons
286	D	DOC	Literature Search Regarding Detection and Quantitation Limit Concepts - June 2002	6/2002	Chuck White	Chip McCarty	12	DynCorp
312	D	TEXT	Chapter 10: Testing Differences Between Monitoring Records when Censored Data Records Exist	1998	Record	E. A. McBean, F.A. Rovers	23 select	In: Statistical Procedures for Analysis of Environmental Monitoring Data and Risk Assessment pp222-242
315	D	TEXT	Chapter 5: Errors and Detection Limits	1992	Record	M.J. Adams	19	In Methods of Environmental Data Analysis by Elsevier Applied Science, p.181-213

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349	D	DOC	Estimating the 99th Percentile: Methods and Difficulties	06/1989	Record	P. Mac Berthouex, Ian Hau	28	The Consortium for Water Pollution Control Research
350	D	DOC	A Study of the Precision of Lead Measurements at Concentrations Near the Method Limit of Detection	12/1991	Record	P.M. Berthouex	25	The Consortium for Water Pollution Control Research
351	D	DOC	A New Model for Measurement Precision at Low Concentrations	02/1992	Record	P.M. Berthouex, D.R. Gan	13	The Consortium for Water Pollution Control Research
393	E	FRN	Guidelines Establishing Test Procedures for the Analysis of Pollutants; Procedures for Detection and Quantitation; Proposed Rule	TBD	Record	USEPA	TBD	Federal Register (TO BE DETERMINED)
394	E	FRN	Guidelines Establishing Test Procedures for the Analysis of Pollutants; Procedures for Detection and Quantitation; Notice of Document Availability and Public Comment Period	TBD	Record	USEPA	TBD	Federal Register (TO BE DETERMINED)
395	E	FRN	Guidelines Establishing Test Procedures for the Analysis of Pollutants; Procedures for Detection and Quantitation; Public Meeting	02/24/2003	Record	USEPA	2	Federal Register (68 FR 8596)
396	E	DOC	Technical Support Document for the Assessment of Detection and Quantitation Concepts	02/03	Record	USEPA	485	DynCorp